

66 The method of claim 65, wherein said deployed antennas have an electromagnetic energy delivery surface size sufficient to create a volumetric ablation without impeding out any one of said deployed antennas when 5 to 200 watts of electromagnetic energy is delivered.

REMARKS

Reconsideration of the rejections set forth in the Office Action dated August 13, 2001 is respectfully requested.

The Applicants petition the Commissioner for a three (3) month extension of time to and including February 13, 2002. A separate petition for the three (3) month extension of time, together with the appropriate fee, is being filed concurrently herewith. Please provide any extension of time that may be necessary and charge any fees which may be due to Deposit Account No. 50-0665, but not to include any payment of issue fees.

Applicants have made amendments to the claims. Upon entry of the amendments, this application will contain claims 53 to 66 pending and under consideration. Claim 53 has been amended and claims 55 to 66 are new claims. The amendments are fully supported by the specification as filed and do not add new matters. Attached hereto is a marked-up version of the changes made to the claims by the current amendment, which is captioned "Version with Markings to Show Changes Made".

I. Amendments

A. Claims

Claims 47-52 are deleted.

Claim 53 has been amended to include the steps of (i) monitoring the temperature of the tissue using temperature sensors positioned at the distal end of the electrodes, and (ii) ceasing the energy delivery when the temperature reaches a predetermined limit. The placement of sensors on the distal ends of the electrodes are specifically recited in figures 1, 2, 3, and 7 and also on p. 10, line 18 to p. 11, line 2. The monitoring and controlling of temperature at the ablation site are recited on page 11, lines 3-11 of the specification.

Claims 55 to 66 are new claims.

B. Drawings

Applicants have amended Fig. 1 to particularly show distal end 14' of the elongated delivery device (trocar 14) and distal end or distal portion 16' of antenna 16. These features are specified in independent claims 53 and 56. Feature 14' is disclosed on page 8, line 21, and feature 16' is disclosed on page 8, line 3. Applicants respectfully request Examiner's approval of the changes made. A substitute drawing sheet of Fig. 1 including the change is submitted herein.

The amendments are fully supported by the specification as filed and do not add new matters. Applicants respectfully request entry of the amendments.

II. Priority Claim

Applicants in the preliminary amendment of July 26, 2001 indicated that claims 47-54 take priority from the subject matter of U.S. Application Serial No. 290,031 which issued as U.S. Patent No. 5,536,267 (the '267 patent). Applicants' basis was that the instant application is a continuation-in-part application of, and incorporates by reference, Application Serial No. 08/608,323 which issued as U.S. Patent No. 5,728,143 (the '143 patent). The '143 patent is a continuation-in-part application of, and incorporates by reference, Application Serial No. 08/515,379 which issued as U. S. Patent No. 5,683,384 (the '384 patent). The '384 application is a continuation-in-part of, and incorporates by reference the '267 patent. Applicants reasoned that since all of the subject matter/disclosure of the '267 patent was properly incorporated by reference and became part of the instant application, thus under USC §120, claims 47-54 in the instant application take priority from the '267 patent and have a priority date of August 12, 1994. Examiner contends that first there is no specific claim of priority to the '267 patent in this application. Additionally, Examiner notes that the inventors, and apparently the assignee, of the '267 patent are entirely different from the inventors of the instant application. As such, the inventors of the instant application cannot claim to be the

inventors of the subject matter of the '267 patent even though the subject matter has been incorporated by reference.

Applicants respectfully request to withdraw the claim of priority to the '267 patent without prejudice. However, Applicants wish to establish common ownership of the '267 patent and the subject application. Applicants respectfully submit that the three above-mentioned patents and the subject application are co-owned by RITA Medical Systems, Inc. The '267 patent and the '384 patent were assigned to ZoMed International, Inc. (ZoMed). ZoMed amended its Article of Incorporation on October 1, 1996 to change the name of the corporation to RITA Medical System, Inc. (RITA). RITA thus becomes the assignee of the '267 and '384 patents. The '143 patent and the subject application were formally assigned to RITA when the respective applications were filed. Accordingly, the '267, '147, '384 patents and the subject application are all assigned to RITA. A copy of the "Certificate of Amendment of Articles of Incorporation" is enclosed for the prosecution file.

III. Drawings

Examiner objects to the drawings under 37 CFR 1.83(a) for not showing the obturator and introducer features which are specified in claims 48, 49, 53 and 54. Claims 48, 49 have been cancelled and claim 53 has been amended to remove reference to the offending features, the amendments thus obviating this objection.

IV. Claim Rejections under 35 USC §102

The Examiner rejected claims 47, 50-52 under 35 USC §102(b) as being anticipated by Edwards et al ('675 patent). In addition, the Examiner f and claims 47-54 under 35 USC §102(e) as being anticipated by LeVeen et al. ('276 patent). The Examiner further rejected claims 47-54 under 35 USC §102(f) as derived support from Edwards et al. (the '267 patent).

Claims 47, 50-52 are cancelled, thus obviating the rejections to these claims. Applicants respectfully traverse the rejection to claims 53 and 54 and further submit that claims 53 and 54 and newly added claims 55-66 are not anticipated by either Edwards et al ('675 patent) or LeVeen et al. ('276 patent).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131.

Applicants respectfully submit that neither Edwards nor LeVeen teaches every element of the present invention as claimed in the amended claims.

As noted by the Examiner, Edwards et al. ('675 patent) teaches an ablation device that includes a plurality of sharpened electrodes which are deployed into tissue. Edwards's device does not have a tissue piecing distal end allowing the elongated delivery device be advanced directly to the tissue ablation site by piercing through tissue as claimed in claim 53. In addition, Edwards et al. does not teach the monitoring of temperature through sensors attached to the distal ends of the antennas as set forth in claims 53 and 57. Further, Edwards fails to disclose antennas that have energy delivery surfaces of sufficient size so that they do not impede out any of the deployed antenna when 5 to 200 watts of energy is delivered as claimed in claim 66. Since Edwards et al. does not disclose every element as set forth in the claims, the invention as claimed is not anticipated. Accordingly, Applicants respectfully request the withdrawal of the rejection of claim 53 under 35 USC 102(b) as being anticipated by Edwards et al. (the '675 patent).

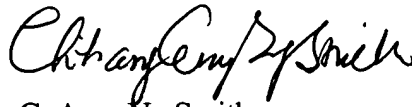
LeVeen failed to teach monitoring impedance for termination of the ablation as claimed in both amended claim 53 and new claim 57 or positioning sensors at the distal end of the antennas for monitoring of impedance as claimed in claims 56 and 58. Therefore, LeVeen et al. does not disclose every element as set forth in the claims, the invention as claimed is not anticipated. Accordingly, Applicants respectfully request the withdrawal of the rejection of claim 53 under 35 USC 102(e) as being anticipated by LeVeen et al.

The Examiner has rejected claims 47-54 under 35 U.S.C. 102 (f) because the Applicants did not invent the claimed subject matter. Applicants have cancelled 47-52 and amended claim 53 to remove reference to the offending features (obturator and introducer) thus obviating this rejection.

In view of the foregoing amendments and remarks, Applicants submit that the claims pending are in condition for allowance. A Notice of Allowance is therefore respectfully solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4404.

Respectfully submitted,



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Date: 2/13/2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

53. [(New)](Amended) A method of volumetric [hyperthermic] ablation of tumorous tissue, [the method]comprising:

providing [a tissue ablation system including an obturator,]a tissue ablation apparatus [including]comprising an elongated delivery device [including]having a tissue piercing distal end and a proximal end, at least one RF electrode [including]having a tissue penetrating distal portion, [the RF electrode being positionable in the delivery device as the delivery device is advanced through tissue], [the]said at least one RF electrode has a non-deployed state when positioned [in]inside said [the]delivery device and a deployed state, in which[the deployed state] said distal portion of said RF electrode [distal portion]exhibiting a curvedly changing direction of travel [in tissue] as the RF electrode is being advanced from the delivery device into a selected tissue site[, and an electrode advancement member coupled to the RF electrode for controllably advancing the RF electrode out of the elongated delivery device into the selected tissue site];

[introducing the obturator through tissue to the selected tissue site;]

[utilizing the obturator to introduce]advancing the elongated delivery device to the selected tissue site by piercing with said tissue piercing distal end;

[advancing]deploying the RF electrode [from the elongated delivery device]into the selected tissue site to define an ablation volume[at the selected tissue site];

delivering energy from the energy delivery device to the selected tissue site through said electrodes to ablate said tissue; [and]

[creating a controlled ablation volume at the selected tissue site.];

monitoring temperature of said tissue using sensors positioned on said electrodes; and
ceasing said energy delivery when said measured temperature reaches a predetermined limit.

-- 55. The method of claim 53 further comprising adjusting, in response to said measured temperature, said energy level to maintain said temperature at a desired value.

56. The method of claim 53, wherein said sensors are positioned at said distal portion of said RF electrodes.

57. A method of ablating a tissue mass comprising:
providing an ablation apparatus comprising a plurality of antennas conductively coupled to an energy source;
positioning said antennas adjacent to a target tissue mass, wherein adjacent distal ends of said antennas define an ablation volume;
delivering energy at a sufficient level which is capable of ablating said target tissue mass to said antennas;
monitoring temperature of said tissue mass using sensors positioned on said antennas as said tissue mass is being ablated; and
ceasing said delivery of energy when said measured temperature reaches a predetermined limit.

58. The method of claim 57 wherein said sensors are positioned at said distal end of said antennas.

59. The method of claim 58 further comprising adjusting, in response to said measured temperature, said energy level to maintain said temperature at a desired value.

60. The method of claim 59 further comprising infusing said tissue with an infusion medium.

61. The method of claim 60, wherein said infusion medium is a chemotherapeutic agent.

62. The method of claim 60, wherein said infusion medium is a conductivity enhancement medium.

63. The method of claim 58, wherein said ablation apparatus further comprises an elongated delivery device having a longitudinal axis, a lumen and a distal end, wherein said plurality of antennas are adapted to position within said lumen when not deployed and to extend through said distal end with curvature in a lateral direction with respect to said longitudinal axis when deployed.

64. The method of claim 63, wherein at least one of said plurality of antennas includes a lumen coupled to an infusion source.

65. The method of claim 59, wherein said energy source is a RF source and said antenna is a RF electrode.

66. The method of claim 65, wherein said deployed antennas have an electromagnetic energy delivery surface size sufficient to create a volumetric ablation without impeding out any one of said deployed antennas when 5 to 200 watts of electromagnetic energy is delivered. --

FIG.—1

State of California



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SECRETARY OF STATE

CORPORATION DIVISION

I, *BILL JONES*, Secretary of State of the State of California, hereby certify:

That the annexed transcript has been compared with the corporate record on file in this office, of which it purports to be a copy, and that same is full, true and correct.

IN WITNESS WHEREOF, I execute
this certificate and affix the Great
Seal of the State of California this

OCT 4 1996



Bill Jones

Secretary of State

BEST AVAILABLE COPY

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CERTIFICATE OF AMENDMENT OF
ARTICLES OF INCORPORATION OF
ZOMED INTERNATIONAL, INC.

FILED
The Office of the Secretary of State
State of California

OCT 2 1996

Bill Jones
Bill Jones, Secretary of State

The undersigned, Patrick J. Burns and Mark B. Weeks, hereby certify that:

1. They are the Acting President and Secretary, respectively, of ZoMed International, Inc., a California corporation (the "Corporation").

2. Article I shall be amended to read in its entirety as follows:

"The name of this corporation is RITA Medical Systems, Inc." -

3. The foregoing amendment of Articles of Incorporation has been duly approved by the Board of Directors.

4. The foregoing amendment of the Articles of Incorporation has been duly approved by the required vote of the shareholders in accordance with Section 902 of the California Corporations Code. The total number of outstanding shares of the corporation is 6,837,336 shares of Common Stock, 9,952,694 shares of Series A Preferred Stock and 18,929,392 shares of Series B Preferred Stock. The number of shares voting in favor of the amendment equaled or exceeded the vote required. The percentage vote required was more than 50% of the Common Stock, Series A Preferred Stock and Series B Preferred Stock, voting together as a single class.

We declare under penalty of perjury under the laws of the State of California that the matters set forth in this certificate are true and correct of our own knowledge.

Executed at Mountain View, California on October 1, 1996.

Patrick J. Burns
Patrick J. Burns

Mark B. Weeks
Mark B. Weeks